

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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Nº 08-CV-1435 (JFB) (WDW)

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CATHERINE M. MEGNA,

Plaintiff,

VERSUS

FOOD & DRUG ADMINISTRATION, DEPARTMENT OF HEALTH  
AND HUMAN SERVICES, SCHERING PLOUGH CORP.  
AND MR. HASSAN,

Defendants.

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**MEMORANDUM AND ORDER**

March 17, 2009

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JOSEPH F. BIANCO, District Judge:

*Pro se* plaintiff Catherine M. Megna (“plaintiff”) brings this action against defendants Food & Drug Administration, a division of the Department of Health and Human Services (“FDA”), Schering-Plough Corporation (“Schering-Plough”), and Fred Hassan (“Hassan”),<sup>1</sup> the CEO of Schering-Plough (collectively, “defendants”), as the administrator cum testamento annexo (“c.t.a.”) of the estate of her sister, Sarah A. Megna (“Megna”). Specifically, plaintiff has asserted a federal claim, pursuant to 42 U.S.C. § 1983, as well as state law claims,

against the defendants arising from their alleged responsibility for the death of her sister. In connection with these claims, plaintiff alleges that her sister was prescribed “Interferon 2a” to treat her kidney cancer and that the drug’s side effects caused her sister’s death. Thus, plaintiff seeks to sue the Schering-Plough defendants for manufacturing the drug “Interferon 2a,” and the FDA for approving that drug, which allegedly caused her sister’s death.

Presently pending before the Court are (1) a motion to dismiss the complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) by defendants Schering-Plough and Hassan (collectively,

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<sup>1</sup> Hassan’s name is misspelled in plaintiff’s caption as “Mr. Hassen, CEO.”

“Schering-Plough defendants”), and (2) defendant FDA’s motion to dismiss the complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

For the reasons set forth below, the Court grants the Schering-Plough defendants’ motion to dismiss the federal claim pursuant to Fed. R. Civ. P. 12(b)(6). Although plaintiff asserts the claim under Section 1983, no such claim can exist as a matter of law given, *inter alia*, the complete absence of any allegation of state action. However, because plaintiff is *pro se*, the Court has liberally construed the complaint and considered whether her allegations can state a claim against the Schering-Plough defendants under any other federal statute. Specifically, the Court has considered whether a *Bivens* claim could be asserted based upon an allegation that the Schering-Plough defendants acted in concert with the FDA to violate plaintiff’s constitutional rights and the Court concludes that, pursuant to Supreme Court precedent, no such cause of action can exist in the instant case as a matter of law, even assuming *arguendo* plaintiff could identify the constitutional right which was violated. In short, the Court is unaware of any federal cause of action that exists to support a claim against the Schering-Plough defendants arising from the alleged death of plaintiff’s sister.<sup>2</sup>

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<sup>2</sup> The Schering-Plough defendants also assert that the complaint was not properly served on them pursuant to Fed. R. Civ. P. 4. Regardless of whether proper service was made, however, the Court finds the complaint should be dismissed for the reasons discussed *infra*.

Similarly, as set forth below, the Court grants the FDA’s motion to dismiss the federal claims against it, pursuant to Fed. R. Civ. P. 12(b)(1). The FDA argues that no federal cause of action exists as a matter of law against the FDA in connection with the allegations contained in the complaint. In particular, no lawsuit can be brought against the United States (including its agencies) under Section 1983 or *Bivens* because such suits are barred under the doctrine of sovereign immunity. The exclusive remedy against the federal government for such alleged torts is the Federal Torts Claims Act (the “FTCA”) and, because plaintiff has failed to exhaust the administrative remedies under the FTCA, the Court lacks subject matter jurisdiction over any such claim.

Finally, because the Court is dismissing the federal claims asserted against the Schering-Plough defendants, the Court declines to exercise supplemental jurisdiction over any state law claims that plaintiff is attempting to assert in the instant lawsuit against them.

## I. BACKGROUND

### A. Facts

The following facts are taken from the complaint and are not findings of fact by the Court.<sup>3</sup> The Court assumes these facts to be

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<sup>3</sup> The Court has also considered the supplemental allegations in what appears to be plaintiff’s attempt at an amended complaint, which was filed in conjunction with her objection to the Schering-Plough defendants’ motion to dismiss. (*See* “Amedded [sic] Complaint” dated August 6,

true for the purpose of deciding this motion and construes them in the light most favorable to plaintiff, the non-moving party. As plaintiff is proceeding *pro se*, the Court has reviewed the complaint broadly, and interpreted it to raise the strongest arguments possible.

Plaintiff, a resident of Bellmore, New York, is captioned as the administrator c.t.a. of the estate of her sister, Sarah A. Megna, who died on October 12, 2003. (Compl. Pt. III, ¶ 3.) Megna had a kidney removed in September of 1999 and suffered from kidney cancer. (Compl. Pt. III, ¶¶ 1-2.) According to the complaint, “Interferon 2a” was prescribed to treat Megna’s cancer, and Megna injected herself three times per week with the drug, which was allegedly recalled on May 24, 2005. (Compl. Pt. III, ¶ 2.) Plaintiff further alleges that the “serious side effects” of Interferon 2a, which left Megna “disorientated and confused,” caused the death of Megna. (Compl. Pt. III, ¶¶ 3, 6.)

Although the complaint is far from clear, plaintiff seems to allege that the FDA, by approving the Interferon 2a drug, “act[ed] in colorbation [sic]” with the Schering-Plough defendants in causing Megna’s death. (Compl. Pt. III, ¶ 7, Pt. IV, ¶ 1.) Plaintiff lists various New York statutes, in apparent support of her claim, including General

Obligations Law § 15-108, CPLR 1404, and CPLR 3405.<sup>4</sup> (Compl. Pt. IV, ¶ 2.) Plaintiff also claims that the Court has jurisdiction pursuant to a “Fedral [sic] Statute” that “govern [sic] claims Joint Torts.” (Compl. Pt. II.) She further captioned this action as one under “42 U.S.C. § 1983,” “Constitutional Right,” “Tort Claims” “CPLR 214b,” “CPLR 1404,” and “CPLR 3405.”

### B. Procedural History

Plaintiff filed this action *pro se* on March 5, 2008.<sup>5</sup> The Schering-Plough defendants submitted their motion to dismiss on July 22, 2008, and plaintiff submitted her opposition on August 7, 2008. The Schering-Plough defendants then filed their reply memorandum on August 29, 2008. On September 30, 2008, the FDA moved to dismiss plaintiff’s complaint. On

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<sup>4</sup> It is unclear, however, why these particular statutes have been referenced by plaintiff, except insofar as plaintiff alleges that defendants are joint tortfeasors in connection with the death of Megna.

<sup>5</sup> Although the docket sheet refers to a related case, *Megna v. Novartis Pharmaceutical Corp. & Assocs.*, No. 04 Civ. 0037 (ADS) (WDW), the Court notes that the subject matter of that lawsuit – involving a foot fungus medication – is unrelated to the instant suit. Moreover, plaintiff’s suit on behalf of her sister against the United States Department of Navy and Northrop-Grumman Corporation – alleging that Northrop-Grumman, which allegedly employed her sister, was responsible for her sister’s kidney cancer – was dismissed because of plaintiff’s inability to represent her sister *pro se*. See *Megna v. U.S. Dep’t of Navy*, 317 F. Supp. 2d 191, 192 (E.D.N.Y. 2004).

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2008.) After carefully reviewing the amended complaint, there are no additional factual allegations contained therein that provide a basis for a federal claim, for the reasons discussed *infra*. Thus, the Court has fully considered the amended complaint and, as discussed below, concludes that it cannot survive a motion to dismiss.

March 3, 2009, the Court issued an Order, in connection with the pending motions to dismiss, seeking additional information from plaintiff to determine whether plaintiff *pro se*, who is not an attorney, is authorized to bring this lawsuit on behalf of her sister. Specifically, the Court directed plaintiff to file a letter providing documentation demonstrating that she had been appointed administratrix or executrix of her sister's estate and documentation regarding the beneficiaries of the estate. Plaintiff made several submissions in response to the Court's Order.

Finally, as reflected on the docket sheet, since the filing of the complaint, plaintiff has submitted additional papers in numerous filings to the Court, as well as some type of injection device contained in one filing, to further articulate her legal and factual positions.

The Court has fully considered all of the parties' submissions.

## II. STANDARD OF REVIEW

"A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). In reviewing a motion to dismiss under Rule 12(b)(1), the court "must accept as true all material factual allegations in the complaint, but we are not to draw inferences from the complaint favorable to plaintiffs." *J.S. ex rel. N.S. v. Attica Cent. Schs.*, 386 F.3d 107, 110 (2d Cir. 2004) (citation omitted). Moreover, the court "may consider

affidavits and other materials beyond the pleadings to resolve the jurisdictional issue, but [it] may not rely on conclusory or hearsay statements contained in the affidavits." *Id.* (citations omitted). "The plaintiff bears the burden of proving subject matter jurisdiction by a preponderance of the evidence." *Aurecchione*, 426 F.3d at 638. The Court may also raise the issue of subject matter jurisdiction at any time *sua sponte*. See, e.g., *McGinty v. New York*, 251 F.3d 84, 90 (2d Cir. 2001) ("Whether a federal court has subject matter jurisdiction is a question that may be raised at any time . . . by the court *sua sponte*." (internal quotation marks omitted)).

In reviewing a motion to dismiss under Rule 12(b)(6), a court must accept the factual allegations set forth in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. See *ATSI Commc'ns., Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007); *Cleveland v. Caplaw Enters.*, 448 F.3d 518, 521 (2d Cir. 2006). The plaintiff must satisfy "a flexible 'plausibility' standard, which obliges a pleader to amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim *plausible*." *Iqbal v. Hasty*, 490 F.3d 143, 157-58 (2d Cir. 2007) (emphasis in original). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 (2007). The Court does not, therefore, require "heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." *Id.* at 570.

Moreover, as the Second Circuit recently emphasized in *Sealed Plaintiff v. Sealed Defendant*, “[o]n occasions too numerous to count, we have reminded district courts that when [a] plaintiff proceeds *pro se*, . . . a court is obliged to construe his pleadings liberally . . . . This obligation entails, at the very least, a permissive application of the rules governing the form of pleadings . . . . This is particularly so when the *pro se* plaintiff alleges that her civil rights have been violated. Accordingly, the dismissal of a *pro se* claim as insufficiently pleaded is appropriate only in the most unsustainable of cases.” 537 F.3d 185, 191 (2d Cir. 2008) (citations and quotation marks omitted); *see also* *Weixel v. Bd. of Educ. of the City of N.Y.*, 287 F.3d 138, 145-46 (2d Cir. 2002) (holding that when plaintiff is appearing *pro se*, the Court shall “‘construe [the complaint] broadly, and interpret [it] to raise the strongest arguments that [it] suggests.’”) (quoting *Cruz v. Gomez*, 202 F.3d 593, 597 (2d Cir. 2000) (alterations in original)); *accord* *Sharpe v. Conole*, 386 F.3d 483, 484 (2d Cir. 2004).

Finally, in connection with a motion to dismiss under Rule 12(b)(6), the Court may only consider the “facts stated in the complaint or documents attached to the complaint as exhibits or incorporated by reference.” *Nechis v. Oxford Health Plans, Inc.*, 421 F.3d 96, 100 (2d Cir. 2005); *accord* *Kramer v. Time Warner Inc.*, 937 F.2d 767, 773 (2d Cir. 1991).<sup>6</sup>

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<sup>6</sup> Here, plaintiff has appended several documents to her complaint, presumably as exhibits, including correspondence letters with Schering-Plough and the Department of Health and Human Services, articles regarding Interferon and Schering-Plough

In this case, both the Schering-Plough defendants and the FDA move to dismiss on both jurisdictional and merits-based grounds. “A court presented with a motion to dismiss under both Fed. R. Civ. P. 12(b)(1) and 12(b)(6) must decide the ‘jurisdictional question first because a disposition of a Rule 12(b)(6) motion is a decision on the merits, and therefore, an exercise of jurisdiction.’” *Coveal v. Consumer Home Mortgage, Inc.*, No. 04 Civ. 4755 (ILG), 2005 WL 2708388, at \*2 (E.D.N.Y. Oct. 21, 2005) (quoting *Magee v. Nassau County Med. Ctr.*, 27 F. Supp. 2d 154, 158 (E.D.N.Y. 1998)); *see also* *Rhulen Agency, Inc. v. Ala. Ins. Guar. Ass’n*, 896 F.2d 674, 678 (2d Cir. 1990) (noting that a motion to dismiss for failure to state a claim may be decided only after finding subject matter jurisdiction).

### III. DISCUSSION

Despite plaintiff’s caption asserting claims under 42 U.S.C. § 1983 (“Section 1983”), the Court construes the complaint liberally to raise its strongest claims/arguments possible, which, in this case, is (1) a potential action for a violation of a federal constitutional right under *Bivens v. Six Unknown Fed. Narcotics Agents*, 403 U.S. 388 (1971), against the Schering-Plough

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that seem to be printed from the Internet, excerpts of Megna’s medical records, including the “Do Not Resuscitate” certification form and Health Care Proxy form signed by Megna that transferred control of her health care decisions to plaintiff. In connection with the motion to dismiss, the Court has considered all of these attached documents, in addition to the allegations asserted in the complaint itself, as well as the supplemental allegations in the amended complaint. *See, e.g., Condit v. Dunne*, 317 F. Supp. 2d 344, 357-58 (S.D.N.Y. 2004).

defendants, and (2) a potential FTCA claim against the FDA. The Court will briefly summarize below the basis for construing the plaintiff's claims in that manner.

With respect to the Schering-Plough defendants, no Section 1983 claim can exist because none of the defendants are alleged to have been state actors, or alleged to have acted in concert with state actors. See *Tancredi v. Metro. Life Ins. Co.*, 378 F.3d 220, 229 (2d Cir. 2004) (“It is settled that conduct by a private entity constitutes state action [for purposes of Section 1983] only when ‘there is a sufficiently close nexus between the State and the challenged action of the [private] entity so that the action of the latter may be fairly treated as that of the State itself.’”) (quoting *Jackson v. Metro. Edison Co.*, 419 U.S. 345, 351 (1974)). As the Supreme Court has noted, “[t]he ultimate issue in determining whether a person is subject to suit under § 1983” is whether “the alleged infringement of federal rights” is “fairly attributable to the State.” *Rendell-Baker v. Kohn*, 457 U.S. 830, 838 (1982) (internal quotations and citation omitted). Thus, given the complete absence of any allegation of state action or a nexus to state action, the claim is more properly framed under *Bivens*. In particular, since plaintiff is apparently attempting to claim that the Schering-Plough defendants acted in concert with the FDA in causing the death of her sister, plaintiff is attempting to assert a cause of action under *Bivens* by alleging that the Schering-Plough defendants, working with the FDA, acted as *federal* agents in violating Megna's constitutional rights. See, e.g., *Hightower v. United States*, 205 F. Supp. 2d 146, 154 n.4 (S.D.N.Y. 2002) (“Although plaintiff purports to invoke Section 1983 and the New York Constitution as bases for his

constitutional claims, his constitutional claims are properly construed as *Bivens* claims because Section 1983 and the New York State Constitution only permit suits against state actors acting under color of state law, and not against the federal government or federal employees acting under federal law.”); *Bender v. Gen. Svcs. Admin.*, 539 F. Supp. 2d 702, 707 (S.D.N.Y. 2008) (“Plaintiff mistakenly professes to rely on 42 U.S.C. § 1983 as grounds for relief . . . to the extent that defendants were clothed with public authority, it was that of federal and not state law, since HWA is a federal contractor providing security to SSA, a federal agency. However, particularly in light of Bender's *pro se* status, we construe her § 1983 claim as a *Bivens* claim.”).

With respect to the FDA, Section 1983 also has no application because, among other things, the state action requirement cannot be met with respect to a federal agency or its officers. See *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 510 (2d Cir. 1994) (“Because AAFES is a federal agency and because the individual defendants are federal officers, the district court construed [plaintiff's] section 1983 claims as *Bivens* claims.”). Moreover, even construing the claim as a *Bivens* claim against the FDA, such a claim must also be dismissed for lack of subject matter jurisdiction because such claims are barred by the doctrine of sovereign immunity. See *id.* at 510 (“Because an action against a federal agency or federal officers in their official capacities is essentially a suit against the United States, such suits are also barred under the doctrine of sovereign immunity unless such immunity is waived. Therefore, to the extent that [plaintiff's] claims constituted a *Bivens* action against AAFES or the individual

federal defendants in their official capacities, they were properly dismissed for want of subject matter jurisdiction.”) (citations omitted). Thus, the Court construes the complaint, which alleges a tort claim against the FDA, as one against the United States for alleged tortious injury under the Federal Torts Claims Act (“FTCA”), 28 U.S.C. § 1346(b) *et seq.* In other words, an action under the FTCA is the sole potential remedy for tortious injury that plaintiff may pursue against the federal government under these circumstances.<sup>7</sup>

Accordingly, liberally construing the complaint, the Court will analyze in turn below a *Bivens* claim against the Schering-Plough defendants and an FTCA claim against the FDA.

#### A. Standing

As an initial matter, the Schering-Plough defendants argue that plaintiff lacks standing to assert any federal claim against them. However, upon the death of an individual who has suffered a constitutional deprivation, the *Bivens* right of action passes to the estate. *See Carlson v. Green*, 446 U.S. 14, 17-18 (1980). Therefore, plaintiff would have standing to bring a *Bivens* claim as administrator c.t.a. of the estate of her sister, if such a claim exists.

Moreover, although not raised by any of the parties, the Court recognizes that “an

administratrix or executrix of an estate may not proceed *pro se* when the estate has beneficiaries or creditors other than the litigant.” *Pridgen v. Andresen*, 113 F.3d 391, 393 (2d Cir. 1997); *accord Weinstein v. Cadman Towers, Inc.*, No. 07 Civ. 3768, 2009 WL 137009, at \*1 (2d Cir. Jan. 21, 2009). In an effort to ensure that plaintiff *pro se* met these requirements, the Court issued an Order on March 3, 2009 which directed plaintiff to do the following: (1) file a letter with the Court by March 16, 2009, stating whether her sister’s estate had any beneficiaries other than herself, or any outstanding creditors; and (2) provide documentation to the Court with the letter demonstrating that she has been appointed administratrix or executrix of her sister’s estate, and documentation regarding the beneficiaries of the estate.

Plaintiff made several submissions to the Court in response to that Order. First, plaintiff provided a Certificate of Letters of Administration from the Surrogate’s Court of the County of Nassau, indicating that plaintiff is the administrator of her sister’s estate. Similarly, although she did not provide documentation regarding the beneficiaries of the estate, plaintiff stated in a handwritten filing to the Court, dated March 12, 2009, that she is not aware of any other beneficiaries. Given the lack of any indication that there exists any beneficiaries or creditors other than plaintiff with respect to the sister’s estate, the above-referenced rule regarding *pro se* representation does not operate as a bar to plaintiff proceeding *pro se* as the administrator to her sister’s estate. However, as set forth *infra*, the claims against the Schering-Plough defendants must be dismissed as a matter of law.

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<sup>7</sup> Although it is unclear from plaintiff’s pleadings, if plaintiff is attempting to bring any independent state tort claims against the United States government, those claims can only be brought under the FTCA and, thus, the Court construes the complaint as such.

Finally, to the extent that the Schering-Plough defendants also argue that plaintiff lacks standing to assert a wrongful death claim under state law, the Court need not address that issue because, given that the federal claims cannot survive a motion to dismiss, the Court is exercising its discretion to decline supplemental jurisdiction over the state law claims. Similarly, Schering-Plough also argues that the complaint does not state a federal cause of action because of various pleading defects (including the absence of any acts indicating which constitutional or federal statutory rights were violated, or how the Schering-Plough defendants caused injury to Megna). Although the Court agrees that plaintiff's complaint suffers from a number of pleading defects, plaintiff's claims (as noted by both the Schering-Plough defendants and the FDA) suffers from more fundamental legal defects, as discussed *infra*, that cannot be corrected by providing plaintiff with leave to amend. Any amendments would be futile because the Court concludes, even if plaintiff provided more specificity regarding some of her allegations, any federal cause of action against the Schering Plough defendants (and the FDA) must fail as a matter of law for the reasons discussed *infra*.

#### B. *Bivens* Claim Against Schering-Plough Defendants

In *Bivens v. Six Unknown Fed. Narcotics Agents*, 403 U.S. 388 (1971), the Supreme Court recognized that private citizens may bring suits for money damages against federal agents, in their individual capacities, for violations of their Constitutional rights. *See id.* at 397. *Bivens* specifically addressed the violation of an individual's Fourth Amendment rights. *See id.*; *see also Liffiton*

*v. Keuker*, 850 F.2d 73, 78 (2d Cir. 1988). However, *Bivens* has subsequently been applied to violations of the Due Process Clause of the Fifth Amendment by the Supreme Court. *See Davis v. Passman*, 442 U.S. 228 (1979). The elements of a *Bivens* claim are: (1) "that a defendant acted under color of federal law" (2) "to deprive plaintiff of a constitutional right." *Tavarez v. Reno*, 54 F.3d 109, 110 (2d Cir. 1995). Here, the Court construes the complaint broadly to allege that the Schering-Plough defendants deprived Megna of her rights pursuant to the Due Process Clause of the Fifth Amendment "under the color of federal law," by acting in concert with the FDA.

However, this claim fails as a matter of law. The Supreme Court has addressed this precise issue, declining to extend *Bivens* to actions against private entities who are alleged to have acted in collaboration with the federal government:

In *Bivens v. Six Unknown Fed. Narcotics Agents*, 403 U.S. 388, 91 S.Ct. 1999, 29 L.Ed.2d 619 (1971), we recognized for the first time an implied private action for damages against federal officers alleged to have violated a citizen's constitutional rights. Respondent now asks that we extend this limited holding to confer a right of action for damages against private entities acting under color of federal law. He contends that the Court must recognize a federal remedy at law wherever there has been an alleged constitutional deprivation, no matter that the victim of the alleged deprivation might have alternative remedies elsewhere, and that the



proposed remedy would not significantly deter the principal wrongdoer, an individual private employee. We have heretofore refused to imply new substantive liabilities under such circumstances, and we decline to do so here.

*Correctional Svcs. Corp. v. Malesko*, 534 U.S. 61, 66 (2001). Therefore, to the extent that the Schering-Plough defendants are alleged to have acted in collaboration with the FDA, their actions cannot form the basis of a lawsuit under *Bivens*. See, e.g., *Bender*, 539 F. Supp. 2d at 708 (“As a private corporation operating under contract with the federal government, HWA is in all material respects in the same position as the defendant in *Malesko*, and it is therefore not subject to a *Bivens* action.”); *Taggart v. Moody’s Investors Service, Inc.*, No. 06 Civ. 3388 (PKC), 2007 WL 2076980, at \*4-\*5 (S.D.N.Y. July 17, 2007) (“While claims for deprivation of due process or eighth amendment rights may be asserted against a private actor under 42 U.S.C. § 1983 where plaintiff alleges state action on the part of the private actor, there is no parallel remedy where the private corporate actor is alleged to have acted under color of federal law.”); *Haughton v. Burroughs*, No. 98 Civ. 3418 (BSJ), 2004 WL 330242, at \*4 (S.D.N.Y. Feb. 23, 2004) (“Applying the *Malesko* holding to the case at bar, it is clear that [plaintiff] cannot bring a *Bivens* action against either Merrill or Morgan, both of which are private corporations. It is likewise clear that he has pursued numerous alternative causes of action, such that here is little need to allow [him] to assert a *Bivens*

claim against Merrill and Morgan.”).<sup>8</sup> In short, under *Malesko*, no *Bivens* claim exists against the Schering-Plough defendants for alleged collaboration with the FDA in causing the death of a person from the use of a prescribed drug, for which numerous alternative remedies against the Schering-Plough defendants exist elsewhere, including in state court.<sup>9</sup>

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<sup>8</sup> Some courts have suggested that, even in the wake of *Malesko*, a *Bivens* action may still be possible against a private individual, as opposed to a private corporation, who is acting under color of federal law, such as individuals working under contract with the federal government. See *Bender*, 539 F. Supp. 2d at 708-12 (collecting cases). Although the Second Circuit has never decided this issue, even assuming *arguendo* that *Bivens* actions were possible under certain circumstances against a private individual allegedly acting under color of federal law, no plausible *Bivens* claim could exist against the CEO of Schering-Plough given the allegations in this case. Specifically, there is no allegation that the CEO was under contract with the FDA or acting under the direction of the FDA in any way. In fact, other than being named in the caption, there are no allegations directed at the CEO in the pleadings. Instead, it is clear that the only alleged connection between the CEO and the FDA is that the CEO was head of the corporation that plaintiff alleges manufactured a drug that was wrongfully approved for use by the FDA. No plausible *Bivens* claim can exist against the CEO under such circumstances even assuming *arguendo* that *Malesko* did not foreclose *Bivens* suits against private actors under certain circumstances. In short, any *Bivens* claim against the CEO is frivolous.

<sup>9</sup> In the alternative, the Court finds that, even if a *Bivens* claim did exist, it would be barred by the statute of limitations. The New York statute of limitations applied by federal courts in *Bivens* actions is three years. *Chin v. Bowen*, 833 F.2d 21,

In sum, whatever causes of action may lie against the Schering-Plough defendants in connection with the death of Megna, no legal basis for any such claims exists as a matter of law under any federal statute given the allegations in the complaint and, thus, plaintiff's federal claims against these defendants are dismissed.<sup>10</sup>

#### C. Federal Torts Claims Act Cause of Action against the FDA

Defendant FDA, a division of the United States Department of Health and Human

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22 (2d Cir. 1987). However, federal law determines when the claim accrues, and “[t]he claim accrues when the plaintiff knows or has reason to know of the harm.” *Eagleston v. Guido*, 41 F.3d 865, 871 (2d Cir. 1994) (quotation marks and citation omitted). The complaint alleges that Megna was prescribed “Interferon 2a” in November 1999 to treat her terminal kidney cancer for an unspecified period of time and that, as a result of unspecified “serious side effects” at an unspecified time, Megna died on October 12, 2003. Therefore, even based on a liberal reading of the allegations in the complaint, the statute of limitations on the *Bivens* claim expired no later than October 12, 2006, or three years after Megna’s death. Because the complaint was filed on March 5, 2008, the *Bivens* claim, in addition to being barred by *Malesko*, is also barred by the applicable statute of limitations.

<sup>10</sup> Furthermore, as discussed *infra*, to the extent that plaintiff may be attempting to allege any state law claims against the Schering-Plough defendants, such as one for wrongful death (which plaintiff seems to allege in her original complaint) or fraud (which seems to be the focus of her amended complaint), the Court declines to exercise supplemental jurisdiction over such claims given that no federal claim can survive a motion to dismiss.

Services, also argues that plaintiff’s complaint should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6). Specifically, the FDA argues that the plaintiff has failed to exhaust administrative remedies and, thus, the court lacks subject matter jurisdiction under the FTCA to adjudicate plaintiff’s claim. (FDA Memorandum of Law in Support, at 1.) The Court agrees and dismisses plaintiff’s complaint against the FDA (or the United States), pursuant to Fed. R. Civ. P. 12(b)(1), for failure to exhaust.<sup>11</sup>

The FTCA provides, in relevant part:

Subject to the provisions of chapter 171 of this title [28 U.S.C. §§ 2671 *et seq.*], the district courts . . . shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission

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<sup>11</sup> The FDA also argues that, to the extent that plaintiff attempts to assert any other constitutional tort claim against the FDA under any other theory of liability (whether state or federal), such a claim is barred by the doctrine of sovereign immunity. The Court agrees with the FDA that any such claim would be barred as a matter of law, for the reasons discussed *supra*, and, therefore, the Court has construed the complaint to assert a claim under the FTCA.

occurred.

28 U.S.C. § 1346(b)(1). By enacting the FTCA, Congress waived the United States' sovereign immunity for claims arising out of torts committed by federal employees. *See id.* "The waiver of sovereign immunity under the FTCA, 28 U.S.C. § 1346(b), is strictly limited to suits predicated upon a tort cause of action cognizable under state law and brought in accordance with the provisions of the FTCA," *Finelli v. Drug Enforcement Agency*, No. 92 Civ. 3463 (PKL), 1993 WL 51105, at \*5 (S.D.N.Y. Feb. 24, 1993), and this constitutes the exclusive remedy for torts committed by federal employees in the course of their duties. *See, e.g., James v. U.S.*, No. 99 Civ. 4238 (BSJ), 2000 WL 1132035, at \*1 (S.D.N.Y. Aug. 8, 2000); *see also Olmeda v. Babbitts*, No. 07 Civ. 2140 (NRB), 2008 WL 282122, at \*5 (S.D.N.Y. Jan. 25, 2008); *Finelli*, 1993 WL 51105, at \*1 ("While this provision does not apply to suits for violation of federal constitutional or statutory rights, it is well settled that it does provide Government employees with absolute immunity against claims of common-law tort." (citing *Rivera v. United States*, 928 F.2d 592, 608 (2d Cir. 1991)). Thus, to the extent that plaintiff alleges that the United States, or any agency thereof, committed common law torts against Megna, any such claim is governed by the FTCA.<sup>12</sup>

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<sup>12</sup> Any tort claim against the FDA, an agency of the federal government, can only be maintained against the United States under the FTCA. *See* 28 U.S.C. § 2679(a). Thus, the Court substitutes the United States for the FDA for the purposes of this analysis. That rule also would apply to the extent that plaintiff is attempting to assert liability against any individual federal employees because there is no

The Supreme Court has clearly stated, in interpreting the statutory text of the FTCA, that "[t]he FTCA bars claimants from bringing suit in federal court until they have exhausted their administrative remedies." *McNeil v. United States*, 508 U.S. 106, 113 (1993); *accord Robinson*, 21 F.3d at 509. Specifically, the FTCA requires that claimants first present their claims to the appropriate federal agency within two years of accrual, and their claims must be denied in writing before claimants may file suit in federal court. *See* 28 U.S.C. §§ 2401(b), 2675(a). "The administrative exhaustion requirement derives from a cardinal principle of law – that the United States, as sovereign, is immune from suits in the courts of law." *Mosseri v. F.D.I.C.*, Nos. 95 Civ. 723 (BJS), 97 Civ. 969 (BSJ), 1999 WL 694289, at \*7 (S.D.N.Y. Sept. 8, 1999). Failure to comply with this requirement results in dismissal of the suit. *See McNeil*, 508 U.S. at 113 ("The FTCA bars claimants from bringing suits in federal court until they have exhausted their administrative remedies. Because petitioner has failed to heed that clear statutory command, the District Court properly dismissed his suit."); *see also Celestine v. Mount Vernon Neighborhood Health Ctr.*, 403 F.3d 76, 82 (2d Cir. 2005) ("The FTCA requires that a claimant exhaust all administrative remedies before filing a complaint in district court. This requirement is jurisdictional and cannot be waived."); *accord Adams by Adams v. United States Dep't of Housing and Urban Dev.*, 807 F.2d 318, 319-20 (2d Cir. 1986); *Willis v. United*

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dispute that any such employees would be acting within the scope of their employment. *See, e.g., Dockery v. Tucker*, No. 97 Civ. 3584, 2006 WL 5893295, at \*7 (E.D.N.Y. Sept. 6, 2006).

*States*, 719 F.2d 608 (2d Cir. 1983); *Keene Corp. v. United States*, 700 F.2d 836, 841 (2d Cir. 1983); *Rawlins v. M&T Mortg. Corps.*, No. 05 Civ. 2572 (RCC), 2005 WL 2143334, at \*4 (S.D.N.Y. Sept. 1, 2005); *Harrison v. Lutheran Med. Ctr.*, No. 05 Civ. 2059 (CBA), 2005 WL 1801626, at \*2-\*3 (E.D.N.Y. July 27, 2005); *Liebers v. St. Albans Med. Ctr.*, No. 99 Civ. 6534 (JG), 2000 WL 235717, at \*1 (E.D.N.Y. Feb. 25, 2000); *Solomon v. United States*, 566 F. Supp. 1033, 1035 (E.D.N.Y. 1982).

In the instant case, plaintiff has failed to exhaust her claims, as required by the FTCA. As the affidavit of Richard Bergeron states, no administrative tort claim with respect to Megna has previously been presented to the FDA or Department of Health and Human Services.<sup>13</sup> (Declaration of Richard Bergeron

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<sup>13</sup> When considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the Court may consider affidavits and other materials beyond the pleadings to resolve jurisdictional questions. *See, e.g., Kamen v. American Tel. & Tel. Co.*, 791 F.2d 1006, 1011 (2d Cir. 1986); *Robinson v. Gov't of Malaysia*, 269 F.3d 133, 141 n. 6 (2d Cir. 2001); *Flanagan v. United States*, 430 F.Supp. 2d 106, 113 (W.D.N.Y. 2006) (“Although Plaintiff asserts that the independent contractor exception to the FTCA is inapplicable here because Plaintiff alleges GSA, not the contractor, was negligent, it is well-settled that the court may look beyond the pleadings to other evidence in the record to determine if subject matter jurisdiction exists.”) (collecting cases); *accord Wilson v. Federal Bureau of Prisons*, No. 07 Civ. 00682 (WDM) (MEH), 2007 WL 4570553, at \*3 (D. Colo. Dec. 21, 2007) (“As plaintiff did not respond to this affidavit with any demonstration that he had fully exhausted his administrative remedies, Magistrate Judge Hegarty concluded that jurisdiction under the FTCA was not appropriate.

¶ 4.) Although plaintiff asserts that on “April 13, 2005 [she] filed FDA form concerning the serious side effects, severe, and agreed by Dept Health & Human Serv.” (Compl. Pt. III, ¶ 5), there is no indication or evidence in the pleadings, the documents attached thereto, or in the numerous submissions that plaintiff has made to this Court since the commencement of the action, of a formal claim that she has filed with the Department of Health and Human Services. Instead, this “FDA form” clearly refers to a report plaintiff made regarding Interferon 2a to the FDA’s MedWatch program, which allows voluntary reporting of adverse events and product problems by patients. (See docket entry [48], MedWatch form, dated April 13, 2005.) However, these types of informal inquiries or complaints are not sufficient to satisfy the FTCA exhaustion requirement. *See, e.g., Grant v. Secretary, U.S. Dep’t of Veterans Affairs*, No. 03-5260, 2004 WL 287125, at \*1 (D.C. Cir. Feb. 4, 2004) (unpublished opinion) (“Appellant argues that his informal letter of complaint to the Director of the Veterans’ Administration Medical Center was sufficient to satisfy the FTCA’s administrative exhaustion requirement, and maintains that ‘legal technicalities’ should not be used to dismiss the action of a pro se litigant. Even liberally construed, however, appellant’s letter does not satisfy the requirements of Section 2401(b).”); *see also Reisman v. Bullard*, No. 00-4286, 2001 WL 856960, at \*2 (6th Cir. June 20, 2001) (unpublished opinion) (“Although it is undisputed that the Reismans made many informal inquiries to the IRS and communicated their displeasure over the

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I agree with Magistrate Judge Hegarty on this issue.”) (citation omitted).

agency's audit of their income tax return, they did not establish that they ever filed a proper FTCA claim with the IRS or that such a claim was denied by the agency."). Thus, the Court finds that plaintiff has failed to properly present an administrative tort claim to the Department of Health and Human Services prior to filing this lawsuit and exhaust the administrative remedy.<sup>14</sup> See, e.g., *Olmeda*, 2008 WL 282122, at \*5 (dismissing claim as barred by the FTCA for failure to exhaust where "neither the ATF nor the FBI has any record of an administrative tort claim filed by [plaintiff] (or an authorized representative of [plaintiff])"); *Liebers*, 2000 WL 235717, at \*1 (dismissing claim under the FTCA where "[t]he defendant has submitted an affidavit from a control clerk at the Department of Veterans Affairs who searched the VA's records and could find no administrative claim filed by [plaintiff]"); *Marsden v. Federal Bureau of Prisons*, 856 F. Supp. 832, 836 (S.D.N.Y. 1994) ("It is undisputed that plaintiff has not filed an administrative tort claim . . . Accordingly, this court lacks jurisdiction

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<sup>14</sup> Moreover, plaintiff's claim against the United States accrued at the time of Megna's death, since the FTCA claim ordinarily accrues at the time of injury. See *Kronisch v. United States*, 150 F.3d 112, 121 (2d Cir. 1998). Megna died on October 12, 2003, and therefore, any claim on her behalf or related to her death had to be presented to the appropriate agency by October 12, 2005, or more than three years ago. It thus appears too late for plaintiff to now file an administrative tort claim. Although the Second Circuit has recognized that the doctrine of equitable tolling could apply with respect to FTCA claims under certain limited circumstances, see *Valdez v. United States*, 518 F.3d 173, 182-85 (2d Cir. 2008), no such circumstances exist here. Plaintiff has failed to demonstrate any basis for equitable tolling.

over the subject matter of this complaint to the extent it alleges a common law tort against the federal defendants.").

Accordingly, the Court dismisses plaintiff's claim against the FDA for lack of subject matter jurisdiction, pursuant to Fed. R. Civ. P. 12(b)(1).

#### D. State Law Claims

In addition to any federal claims contained in the complaint, the Schering-Plough defendants argue that the Court should dismiss any state law claims that plaintiff is attempting to assert because such claims are barred by the applicable statute of limitations, the complaint fails to state a claim upon which relief may be granted, and plaintiff lacks standing to bring such claims.

"In the interest of comity, the Second Circuit instructs that 'absent exceptional circumstances,' where federal claims can be disposed of pursuant to Rule 12(b)(6) or summary judgment grounds, courts should 'abstain from exercising pendent jurisdiction.'" *Birch v. Pioneer Credit Recovery, Inc.*, No. 06 Civ. 6497T, 2007 WL 1703914, at \*5 (W.D.N.Y. June 8, 2007) (quoting *Walker v. Time Life Films, Inc.*, 784 F.2d 44, 52 (2d Cir. 1986)). In the instant case, the Court, in its discretion, "decline[s] to exercise supplemental jurisdiction over [plaintiff's] state law claims [because] it has dismissed all claims over which it has original jurisdiction." *Kolari v. N.Y.-Presbyterian Hosp.*, 455 F.3d 118, 121-22 (2d Cir. 2006) (quoting 28 U.S.C. § 1367(c)(3)) (internal quotation marks omitted) ("If the federal law claims are dismissed before trial . . . the state claims should be dismissed as well."); *Karmel v. Liz*

*Claiborne, Inc.*, No. 99 Civ. 3608 (WK), 2002 WL 1561126, at \*4 (S.D.N.Y. July 15, 2002) (“Where a court is reluctant to exercise supplemental jurisdiction because of one of the reasons put forth by § 1367(c), or when the interests of judicial economy, convenience, comity and fairness to litigants are not violated by refusing to entertain matters of state law, it should decline supplemental jurisdiction and allow the plaintiff to decide whether or not to pursue the matter in state court.”). Accordingly, pursuant to 42 U.S.C. § 1367(c)(3), the Court declines to retain jurisdiction over the remaining state law claims given the absence of any federal claims that survive a motion to dismiss, and dismisses such state law claims without prejudice.<sup>15</sup>

#### IV. CONCLUSION

For the foregoing reasons, the Schering-Plough defendants’ motion to dismiss plaintiff’s federal claims, pursuant to Rule

12(b)(6) of the Federal Rules of Civil Procedure, is granted. Defendant FDA’s motion to dismiss plaintiff’s lawsuit against the FDA, pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure, is also granted.

The Court declines to exercise supplemental jurisdiction over any state law claims being asserted as to the Schering-Plough defendants and, thus, those state law claims are dismissed without prejudice.<sup>16</sup> The Clerk of the Court shall enter judgment accordingly and close this case.

The Court certifies pursuant to 28 U.S.C. § 1915(a)(3) that any appeal from this order would not be taken in good faith and therefore *in forma pauperis* status is denied for purpose of an appeal. *Coppedge v. United States*, 369 U.S. 438, 444-45 (1962).

SO ORDERED.

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JOSEPH F. BIANCO  
United States District Judge

Dated: March 17, 2009  
Central Islip, New York

\* \* \*

Plaintiff is proceeding *pro se*. The attorney for defendants Schering-Plough and Fred Hassan is Casey D. Laffey, Reed Smith

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<sup>15</sup> To the extent that plaintiff could have brought any state law claims against the Schering-Plough defendants pursuant to this Court’s diversity jurisdiction, plaintiff has given no indication that such a basis for federal jurisdiction is being asserted or exists, and it is the burden of the plaintiff to establish subject matter jurisdiction by a preponderance of the evidence. *See Aurecchione v. Schoolman Transp. Sys., Inc.*, 426 F.3d 635, 638 (2d Cir. 2005). Instead, plaintiff claims that the jurisdiction of the Court is “involved [sic] pursuant to Federal Statute govern claims” (Compl. Pt. II), and plaintiff checked “federal question” jurisdiction as the basis of jurisdiction on the civil cover sheet attached to her complaint. Thus, plaintiff has failed to assert or demonstrate that diversity jurisdiction exists and, as noted above, the Court in its discretion declines to exercise supplemental jurisdiction over any state law claims.

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<sup>16</sup> As noted *supra*, even assuming *arguendo* that plaintiff is attempting to assert state law tort claims against the United States, those claims are barred outside the FTCA and, thus, the Court construed them as an FTCA claim.

LLP, 599 Lexington Avenue, 29<sup>th</sup> Floor, New York, NY 10022. The attorney for the Food & Drug Administration, Department of Health and Human Services is Vincent Lipari, Assistant U.S. Attorney, Office of the

United States Attorney, Eastern District of New York, 610 Federal Plaza, 5<sup>th</sup> Floor, Central Islip, New York 11722.